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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,795	07/14/2003	Alan G. Barbour	UTSK:352USC1	3545

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EXAMINER	
OGUNBIYI, OLUWATOSIN A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,795	BARBOUR ET AL.	
	Examiner	Art Unit	
	Oluwatosin Ogunbiyi	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-68* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-48, 50-68* is/are rejected.

7)☒ Claim(s) *49* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date [redacted]/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

1. Applicants are requested to update the status of co-pending application(s) and whether patented or abandoned should also be included. If a co-pending application has become a patent, the expression "now patent No. *******" should follow the filing date of the application. Such information is missing in the priority statement for application serial No. 09/275/506 now U.S. patent No. 6,617,441.

Drawings

2. The drawings were received on 7/14/03. These drawings are acceptable.

Information Disclosure Statement

3. The information disclosure statement filed 8/25/03 has been considered. An initialed copy is enclosed.

Claim Objections

4. Claim 49 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, claim 49 is drawn to a purified nucleic acid segment comprising at least 14 contiguous nucleotides of SEQ ID NO: 1 wherein the purified nucleic acid encodes a polypeptide comprising the amino acid sequence of SEQ ID NO: 2. In view of the Wobble hypothesis, whereby some amino acids are specified by more than one triplet codon (usually differing at the third position), a polypeptide encoded by nucleotide sequences

outside of the 14 contiguous nucleotides of SEQ ID NO: 1 can be encoded by more than one nucleotide sequence. Therefore, claim 49 appears broader in scope than claim 37. This issue is best resolved by Applicants amending the claims to indicate that, for example, "wherein the purified nucleic acid segment comprises residues 1 to 641 of SEQ ID NO: 1..."

Non- Statutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 37-44, 46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4 of U.S. Patent No. 6,617,441.

In the instant case, the claims are drawn to nucleic acids segments comprising a nucleotide sequence of at least 14 contiguous nucleotides of SEQ ID NO: 1, or its complement.

Claims 2-4 of U.S. Patent No. 6,617,441 are drawn to a purified nucleic acid segment comprising the nucleotide sequence of SEQ ID NO:4 or SEQ ID NO: 26 or their complement.

Although the conflicting claims are not identical, they are not patentably distinct from each other because SEQ ID NO: 4 and SEQ ID NO: 26 share 330 and 591 contiguous nucleic acid residues respectively with SEQ ID NO: 1 (See attached sequence search print outs for the alignment of SEQ ID NO: 1 of instant application with SEQ ID NO:4 and 26 of U.S. Patent No. 6,617,441). In addition, in view of the sequence alignment, SEQ ID NO: 4 contains more than one *B. lonestari* sp. nov.-specific nucleotide namely T141, A193, G199, G228, A231, T269, C270. T271, A273, A300, T308, G315, A376, G380, A406, G418, G423. Similarly, SEQ ID NO: 26 contains the following *B. lonestari* sp. nov.-specific nucleotides: G70, G96, T141, A193, G199, G228, A231, T269, C270. T271, A273, A300, T308, G315, A376, G380, A406, G418, G423, G505, G510, G546.

Therefore, claims encompassing nucleic acid segments comprising at least 14 contiguous nucleotides of SEQ ID NO: 1 of the instant application are obvious over claims 2-4 of U. S. Patent No. 6,617,441 because the claims of the patent anticipate the instantly claimed invention.

6. Claims 37-44, 46, 50-58, 62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4 of U.S. Patent No. 6,617,441 in view of Promega catalog, 1992/93 page 125.

The claims are drawn to nucleic acid segments of SEQ ID NO: 1 and expression vectors and a host cell comprising said expression vectors and nucleic acids.

The teachings of claims 2-4 of U.S. Patent No. 6,617,441 are set forth supra.

Promega catalog, 1992/93 page 125 teaches that it is routine in the art to use *E. coli* LE392 for genomic and cDNA cloning and also as host cells for expression vectors for the production of fusion proteins. Promega et al also teaches expression vectors for LE392.

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to clone the DNA segments of U.S. Patent No. 6,617,441 into commercially available expression vectors and then using E. *coli* host strain LE392 of Promega for the purposes of heterologous protein expression thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

7. Claim 37-44, 46 and 64-68 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4 of U.S. Patent No. 6,617,441 in view of Boehringer Mannheim Biochemicals, 1991 pages 502 and B7-B8.

In the instant case, the claims are drawn to kits for the detection of *B. lonestari* comprising nucleic acids segments comprising a nucleotide sequence of at least 14 contiguous nucleotides of SEQ ID NO: 1, or its complement.

The teachings of claims 2-4 of U.S. Patent No. 6,617,441 are set forth supra.

Boehringer Mannheim Biochemicals, 1991 pages 502 and B7-B8, teach that it is conventional in the art to package nucleic acid detection kits in multiple pre-packaged reagents (see abstract recitation at least vial 1 and bottle).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to package all nucleic acid segments of U.S. Patent No. 6,617,441 in a kit format for the detection of Lyme disease because kits provide convenience and economy to the consumer and Boehringer Mannheim Biochemicals teach that nucleic acid detection kits were routine in the art and have individually packaged reagents, thus resulting in the instantly claimed invention with a reasonable expectation of success.

8. Claims 37-44, 46, 50-59, 61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4 of U.S. Patent No. 6,617,441 in view of Robinson et al (WO93/08208, April 1993).

The claims are drawn to nucleic acid segments of SEQ ID NO: 1 and expression vectors comprising said nucleic acids.

The teachings of claims 2-4 of U.S. Patent No. 6,617,441 are set forth supra.

Robinson et al teach that it is routine in the art to clone DNA sequences in plasmid expression vectors (e.g. pBR322) for the expression of polypeptides in *E.coli* (pages 17-21 example 2, page 28-29 example 7). Robinson et al also teach that it is routine to clone nucleic acids into plant, bacterial, yeast, insect, viral and/or mammalian vectors for expression of polypeptides in the respective expression systems (page 9 paragraph 1).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to clone said the DNA segments of U.S. Patent No. 6,617,441 (as set forth supra) into commercially available plasmid and viral expression vectors for the purposes of heterologous protein expression thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success.

9. Claims 37-44, 46, 50-60, 62 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4 of U.S. Patent No. 6,617,441 in view of Berkner et al (Current Topics in Microbiology and Immunology 1992 vol 158 pp 39-66).

In the instant case, the claims are drawn to nucleic acid segments of SEQ ID NO: 1 and expression vectors (viral and adenoviral vectors) and a host cell comprising said expression vectors and nucleic acids.

The teachings of claims 2-4 of U.S. Patent No. 6,617,441 are set forth supra.

Berkner et al teaches the expression of heterologous sequences in Adenoviral vectors. Berkner et al further teaches the generation of Adenovirus recombinants (page 47 last paragraph), the advantages of using adenovirus as a vector for overexpression of foreign genes due to the potent strength of the Major Late Promoter (MLP), coupled with the ability of Adenovirus to shut off cellular protein synthesis at late times and the appropriate post-translational processing and subcellular targeting (page 45 last

bridging paragraph and page 46 first paragraph) and their broad host range specificity (pp 46 last bridging paragraph and page 47 first paragraph).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to clone the DNA segments of U.S. Patent No. 6,617,441 into an Adenovirus vector for protein expression because Berkner et al teaches the use of Adenovirus vectors for cloning and overexpression of foreign genes thus resulting in the instant invention with a reasonable expectation of success.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

10. Claim 37-45, 47-48, 50-64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The claims are drawn to isolated nucleic acid sequences that have at least 14 consecutive nucleotides of SEQ ID NO: 1. The specification specifically contemplates the genus of " A further embodiment of the present invention is a nucleic acid segment

that comprises at least a 10-14 nucleotide long stretch that corresponds to or is complementary to, the nucleic acid sequence of SEQ ID NO: 1 and includes an allele as described in table 2 (specification page 11 last paragraph). This paragraph of the specification only supports a nucleic acid segment at least 10-14 nucleotides long and [in combination] with an allele from Table 2. The genus now claimed, " A purified nucleic segment comprising ... at least 14 contiguous nucleotides of SEQ ID NO: 1, or its complement", does not find support by the specification as originally filed. Therefore, the claims broaden the scope of the specification and thus are deemed new matter.

Furthermore, the same paragraph of the specification teaches the other claimed stretches of nucleotides '... and includes an allele as described in table 2." In the absence of a recitation that these claimed stretches of nucleic acids also include an allele as described in Table 2, these other claims also include new matter.

With respect to claims 47 and 48, the specification at page 19, second paragraph states that "...an oligonucleotide comprising a nucleotide sequence of about 12 to about 30 nucleotides from SEQ ID NO:I that includes at least one *B. lonestari* sp. nov. specific nucleotide or species-specific combination of nucleotides from Table 2 or 3, or a complement thereof, under conditions allowing hybridization to form a duplex, wherein duplex formation indicates the presence of *B. lonestari* sp. nov. Preferably, the nucleotide sequence comprises the sequence GGTGTTCAAGCG, SEQ ID NO: 7 or GTTCAACCAGCT, SEQ ID NO: 8." Therefore, SEQ ID NO: 7 and 8 are presented as oligonucleotides with an upper length limit (to about 30 nucleotides). This passage fails the written description support for nucleic acids comprising SEQ ID NO: 7 and 8 that are longer than about 30 nucleotides in length from SEQ ID NO: 1. SEQ ID NO: 7 and 8, represent particularly preferred embodiments of oligonucleotides that have a defined length as discussed in this passage. Therefore, the claims are deemed new matter as they broaden the scope of the concept set forth in the written description as filed (page 19 second paragraph).

11. Claims 50-63 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to expression vectors comprising any 14 or more consecutive nucleotides and host cells comprising these. Any random 14 consecutive nucleotides from SEQ ID NO: 1, may or may not encode a peptide or protein related to SEQ ID NO: 2 of the specification because the claims allows the expression to start from any of a variety of reading frames. It is unclear exactly what the composition of any peptide will be if it is expressed by a nucleic acid which has a different reading frame from that explicitly set forth by corresponding to SEQ ID No: 2. For example, if the reading frame shifts one or two nucleotides, all the codons downstream of that insertion or deletion will be frameshifted. In such a case, it is highly unlikely that the protein or peptide expressed therefrom will have little in common structurally or functionally with the protein of SED ID NO: 2, that is specifically disclosed as being encoded by SEQ ID NO: 1. In this regard, applicant has not enabled the scope of the inventions as claimed for host cells comprising expression vectors comprising those nucleic acids which would produce altered proteins.

The specification discloses specific variants of the *B. lonestari* flagellar proteins and nucleic acids encoding them. The proteins have specific immunological and biological properties, which are the result of its primary acid sequence as encoded by the nucleic acid sequence. Applicants' claims encompass frameshifted protein variants that when produced from the nucleic acid sequence does not predict a protein having all the identifiable properties of the protein variants as disclosed. Hence, expression vectors and host cells used to produce such variants to produce such undisclosed peptides, which result from these frameshifts, are not enabled.

In addition, many of the claims recite a specific number of consecutive nucleic acids that do not correspond to peptide lengths of the specification. For example, the claims require expression of at least 14 consecutive nucleotides. There is no protein that is encoded by 14 nucleotides. Each amino acid requires a triplet codon and as such 14 consecutive nucleic acids does not provide for any peptide that corresponds to the

specification. The skilled artisan would be forced into undue experimentation to make and use the instantly claimed invention because it is not clear that the nucleic acid ranges claimed and the frameshifts claimed provide for a functional specific *B. lonestari* flagellar protein variant. Although the skilled artisan might envision making a great number of changes of a reference nucleic acid sequence in accordance with applicant's disclosure, it is unclear exactly that the protein which is expressed therefrom would be the specific *B. lonestari* flagellar protein variants disclosed in the applicant's invention. These altered nucleic acids would encode a polypeptide, which would vary from the disclosed amino acid sequences in some unknown or unpredictable manner.

As to the embodiment claiming an "expression vector comprising the... complement", it is noted that "complementary" is routinely used in the art to describe the opposite, reverse complement strand of a given DNA sequence. As such, the claims read upon expressing a polypeptide encoded by a sequence antisense to the coding strand of the flagellin proteins or the antisense of SEQ ID NO: 1. It is well known that antisense sequences do not encode products related to the sense strand, for example, the 5'-3' directionality is reversed and therefore each codon triplet is read in the reverse orientation (encoding a different amino acid) and the N and C terminal of the encoded product is reversed. Applicant has not provided any guidance or working examples which would lead one of skill in the art to predict, firstly, that the antisense strand of SEQ ID NO: 1 does in fact, encode a protein product (e.g. start sequences, methionine codon, a substantial open reading frame, stop and other termination signals). Further, one of skill in the art would not predict such a product would be structurally or functionally related to SEQ ID NO: 2 and applicant has not provided any potential means of using such an unrelated protein product.

In view of the forgoing, it would require undue experimentation to make and use the claimed invention.

Claim Rejections - 35 USC § 102 and 103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 37-40, 50-52, 59, 61- 62 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Robinson et al (WO93/08208, April 1993).

The claims are drawn to nucleic acid segments of SEQ ID NO: 1 and expression vectors and a host cell comprising said expression vectors and nucleic acids.

SEQ ID NO: 1 of Robinson et al has 29 consecutive residues in common with SEQ ID NO: 1 (see alignment from sequence search and page 37-39 of WO93/08208, April 1993). Nucleic acid residues 862-890 of Robinson et al (SEQ ID NO: 1) are 100% identical to residues 1-29 of SEQ ID NO: 1.

Robinson et al teach a DNA sequence comprising the 29 consecutive nucleotide residues (as set forth above) cloned in a plasmid expression vector (derived from pBR322) for the expression of polypeptides in *E.coli* (pages 17-21 example 2, page 28-29 example 7). The polypeptides are used as reagents for the detection of an antibody to the causative agent of Lyme disease (page 29-30 example 8). Robinson et al also teach that said nucleic acids can be cloned into plant, bacterial, yeast, insect, viral and/or mammalian vectors for expression of polypeptides in the respective expression systems (page 9 paragraph 1).

13. Claims 37-40 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Picken et al (WO91/19814, December 1991).

The claims are drawn to nucleic acid segments of SEQ ID NO: 1 comprising at least 14 contiguous nucleotides of SEQ ID NO: 1.

Picken et al teach a nucleic acid that has 44 consecutive nucleotide residues in common with SEQ ID NO: 1 (See sequence search results and Picken et al (page 8 last paragraph and Fig. 1B)). Residues 301-344 of Picken et al are 100% identical to residues 1-44 of SEQ ID NO: 1 (see attached alignment). Picken et al disclose probes

and primers comprising nucleic acids and associated assay reagents useful for detecting Lyme disease.

14. Claims 37-40, 50-52, 59, 61-63 are rejected under 35 U.S.C 103 (a) as being unpatentable over Robinson et al (WO93/08208, April 1993) in view of Promega catalog 1992/93 pg 125.

The claims are drawn to nucleic acid segments of SEQ ID NO: 1 and expression vectors and a host cell comprising said expression vectors and nucleic acids.

Robinson et al is set forth supra. Robinson et al does not teach *E. coli* LE392 as host cell.

Promega catalog, 1992/93 page 125 teaches that it is routine in the art to use *E. coli* LE392 for genomic and cDNA cloning and also as host cells for expression vectors for the production of fusion proteins. Promega et al also teaches expression vectors for LE392.

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to clone said the DNA sequence of Robinson et al (as set forth supra) into commercially available expression vectors and then using E. *coli* host strain LE392 of Promega for the purposes of heterologous protein expression thus resulting in the practice of the instantly claimed invention with a reasonable expectation of success because Robinson et al teaches that protein expression is desirable.

15. Claims 37-40, 50-52, 59, 60-62 are rejected under 35 U.S.C 103 (a) as being unpatentable over Robinson et al (WO93/08208, April 1993) in view of Berkner et al (Current Topics in Microbiology and Immunology 1992 vol 158 pp 39-66).

The claims are drawn to nucleic acid segments of SEQ ID NO: 1 and expression vectors and a host cell comprising said expression vectors and nucleic acids.

Robinson et al is set forth supra. Robinson does not teach cloning of a DNA sequence comprising 29 consecutive residues of SEQ ID NO: 1 into an adenoviral expression vector for heterologous protein expression.

Berkner et al (Current Topics in Microbiology and Immunology 1992 vol 158 pp 39-66) teaches the expression of heterologous sequences in Adenoviral vectors. Berkner et al further teaches the generation of Adenovirus recombinants by insertion of foreign genes into the Adenovirus genome as part of a self sufficient expression cassette that includes a promoter or substitution or insertion into the E1 or E3 region downstream of the respective early promoters (page 47 last paragraph). Berkner et al teaches that it is advantageous to use adenovirus as a vector for overexpression of foreign genes due to the potent strength of the Major Late Promoter (MLP), coupled with the ability of Adenovirus to shut off cellular protein synthesis at late times and the appropriate post-translational processing and subcellular targeting are observed (page 45 last bridging paragraph and page 46 first paragraph). Other advantages of using adenoviral vectors are discussed such as their broad host range specificity, ability to penetrate cells, efficient transformation frequency and ability to make Adenovirus recombinants with relative ease (pp 46 last bridging paragraph and page 47 first paragraph).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to clone the DNA sequence of Robinson et al (as set forth supra) into an Adenovirus vector for protein expression because Berkner et al teaches the use of Adenovirus vectors for cloning and overexpression of foreign genes and Robinson et al teach the cloning of a DNA sequence (as set forth supra) into vectors for polypeptide expression, thus resulting in the instant invention with a reasonable expectation of success.

16. Claims 37-40, 64-66 are rejected under 35 U.S.C 103 (a) as being unpatentable over Picken et al (WO91/19814, December, 1991) in view of Boehringer Mannheim Biochemicals, 1991 pages 502 and B7-B8).

The claims are drawn to nucleic acid segments of SEQ ID NO: 1 and kits for the detection of *B. lonestari* comprising said nucleic acids.

Picken et al is set forth supra. Picken et al does not teach all of the reagents for performing hybridization in a kit format.

Boehringer Mannheim Biochemicals, 1991 pages 502 and B7-B8, teach that it is conventional in the art to package nucleic acid detection kits in multiple pre-packaged reagents (see abstract recitation at least vial 1 and bottle).

It would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to package all the nucleic acid probes, primers and hybridizing reagents of Picken et al in a kit format for the detection of Lyme disease because kits provide convenience and economy to the consumer and Boehringer Mannheim Biochemicals teach that nucleic acid detection kits were routine in the art and have individually packaged reagents and Picken et al teach an assay useful for the detection of Lyme disease.

Status of the Claims

No claim is allowed

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Oluwatosin Ogunbiyi whose telephone number is 571-272-9939. The examiner can normally be reached on M-F 8:30 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert Navarro can be reached on 571-272-0861.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Oluwatosin Ogunbiyi
Examiner Art Unit 1645

PATRICIA A. DUFFY
PRIMARY EXAMINER